

PATENT APPLICATION
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of

Docket No: Q95704

Joon-Haeng RHEE, et al.

Appln. No.: 10/585,880

Group Art Unit: 1645

Confirmation No.: 4676

Examiner: Nina Archie

Filed: May 3, 2007

For: MUCOSAL VACCINE ADJUVANTS CONTAINING BACTERIAL FLAGELLINS AS
AN ACTIVE COMPONENT

RESPONSE TO RESTRICTION AND ELECTION OF SPECIES REQUIREMENTS

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This responds to the Restriction and Election of Species Requirement dated September 4, 2008. In response to the Restriction Requirement, Applicants elect for examination **Group 1 - claims 1-3 and 6-7**, drawn to a mucosal vaccine adjuvant. This election is made with traverse.

This responds to the Election of Species Requirement, dated September 4, 2008. The Examiner has identified the application as containing claims directed to more than one distinct species. The Examiner has required the Applicants to elect a single disclosed specie for prosecution on the merits to which the claims shall be restricted. The Examiner believes there are no generic claims. Applicants have been advised that a response to this requirement shall include an identification of the species that is elected and a listing of all claims readable thereon.

In response to the Examiner's requirement, Applicants elect:

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Species A of Flagellins - *Vibrio vulnificus* on which claims 2, 3, 6 and 7 are readable; and

Species B of Adjuvant - Vaccine against tetanus toxoid and so on, on which claim 6 is readable.

Furthermore, in response to Nucleotide Sequence Election Requirement to Group I, Applicants select a DNA and amino acid combination from the SEQ ID NOS. 3-4 in the mucosal vaccine on which claims 3, 6 and 7 are readable as drawn to flaB.

Applicants' traversal to the Requirements are as follows.

The Examiner asserts that the inventions listed Groups I and II do not relate to a single general inventive concept under PCT Rule 13.1 because the technical feature of Group I is a mucosal vaccine adjuvant and this feature is anticipated by McSorley et al., 2002, Journal of Immunology Vol. 169, pp.3941-3919. In particular, the Office asserts that McSorley teaches flagellin has important implications for vaccine development and the generation of CD4 T cell responses to enteric bacteria.

Applicants respectfully disagree with the Office's assertion and submit that the claimed invention shows superior activity over the art.

As shown in Jeong et al., A Bacterial Flagellin, *Vibrio vulnificus* FlaB, Induces Human Dendritic Cell Maturation, Journal of Bacteriology and Virology 2005, Vol. 35, No. 3, pp. 209-216 (which is published after the earliest effective filing date of the instant application; a copy is submitted as APPENDIX A), flagellins A, B, C, D, E and F of the *Vibrio vulnificus* have TLR-5 agonistic activity. The experimental data, which is submitted as an APPENDIX B, show that the bacterial flagellins of the present invention have a slight protecting effect in the systemic

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immune system, whereas they have a superior activity in the mucosal immune system (See "Data showing superiority of a flagellin as a mucosal adjuvant"). In the result of the experiment, the intraperitoneally (systemic route) infected mice did not show the effect of protecting against *V. vulnificus* (0% survival) [See FIGS. 1 and 2(a) in Data showing superiority of flagellin as a mucosal adjuvant"], whereas all of the orally (mucosal route) infected mice were completely protected [See FIG. 2(b) in Data showing superiority of a flagellin as a mucosal adjuvant"].

Therefore, Applicants respectfully submit that the special technical feature of the invention defined in the claims exists.

Applicants submit that if any of the elected claims is found to be allowable, claims dependent therefrom should similarly be considered allowable in the same application. Furthermore, Applicants respectfully request that the non-elected species be considered on the merits when the Office determines that the elected species are free of prior art.

Applicants reserve the right to file a Divisional Application directed to non-elected claims 4-5.

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The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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Enclosure: APPENDICES A & B